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John V. Hanley, Reg. No. 38,171

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of

Inventor: David T. Pollock, et al.

Serial No. 09/546,966

Filed: April 11, 2000

For: SINGLE-PIECE THICK-WALLED ENDOPROSTHESIS

Date: December 12, 2005

Examiner: Vy Q. Bui

Group Art Unit: 3731

Client ID/Matter No. ENDOS-51639

APPELLANT'S BRIEF (CFR § 1.192)

MS: Appeal Brief Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appellant's Brief is being filed in response to a final Office action dated June 23, 2005 and an Advisory Action dated September 14, 2005. The Notice of Appeal and Petition For a One Month Extension of Time along with the fees required under § 1.17 were submitted on October 21, 2005. Submitted herewith is the fee required under 37 CFR § 41.20 (b)(2). In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

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This brief contains items under the following headings, and in the order set forth below:

I. REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF AMENDMENTS

V. SUMMARY OF CLAIMED INVENTION

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

VII. ARGUMENT

VIII. CLAIMS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation, 111 Monument Circle, 29th Floor, Indianapolis, IN 46204-5129.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1-24 and 36-39

B. Status of All of the Claims

Each of pending claims 1-3, 5, 7-10, 12-15, 17, 20, 22, 23, 36, 38 and 39 stand as finally rejected under either 35 U.S.C. § 102(e) or 35 U.S.C. § 103(a). Claim 6 was objected to and claims 4, 11, 16, 18, 19, 21 and 24 have been withdrawn from consideration.

C. Claims on Appeals

The claims on appeal are each of pending claims 1-24 and 36-39.

IV. STATUS OF AMENDMENTS

On June 23, 2005, claims 1-3, 5, 7-9, 12-15, 17, 20, 22, 36, 38 and 39 were rejected under 35 U.S.C. § 102(e) as being anticipated by Drasler et al. (6,245,101; Exhibit A). Additionally, claims 10 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Drasler et al. in view of Taheri (5,617,878; Exhibit B) and claim 37 was rejected under § 103(a) in view of Drasler et al.

In response thereto, the Applicants filed a paper dated August 23, 2005 arguing for the allowance of the pending claims. Subsequently, the Examiner issued an Advisory Action on September 14, 2005. The September 2005 Advisory Action indicated that the Examiner did not believe that Applicants' arguments were persuasive.

V. SUMMARY OF CLAIMED INVENTION

As set forth in the specification of the present application, the apparatus recited in independent claims 1, 12 and 17 relates to an endoluminal prosthesis and more particularly, to an expandable and compressible prosthesis for repairing corporeal lumens. Further, the prosthesis

forms a cylinder including a series of curved beams and merge sections which define cells (Page 7, lines 7-24; FIG. 8).

The beams of the claimed apparatus have a cross-section which is greater in a radial direction (thickness) than in the circumferential direction (width). The beams also can be continuously curved to reduce or minimize stress concentrations in the structure (Page 3, lines 11-15).

Moreover, the prosthesis of the present invention can be formed from a single integrated structure without welds or fasteners (Page 4, line 3). To create the device, cells are removed from a cylinder and thus, the present invention is characterized by connecting points which are less bulky and having reduced stress concentrations (Page 2, lines 17-19; Page 4, lines 4-6).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-3, 5, 7-9, 12-15, 17, 20, 22, 36, 38 and 39 were improperly rejected under 35 U.S.C. § 102(e) as being anticipated by Drasler et al.; whether claims 10 and 23 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Drasler et al. in view of Taheri et al.; and whether claim 37 was improperly rejected under § 103(a) in view of Drasler et al.

VII. ARGUMENT

A. Overview

In order for there to be anticipation under 35 U.S.C. § 102(e), each and every limitation must be taught by the prior art reference being cited by the Examiner.

Moreover, a tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed

invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Additionally, it is submitted that as is supported by MPEP Section 2144, by mischaracterizing the cited art, the Examiner has not presented a convincing line of reasoning supporting the rejection of the claims. Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). Since the art appears to lack the teaching of the limitations recited in the claims, should the rejections be based upon facts within the personal knowledge of the Examiner, the data supporting that knowledge should be stated as specifically as possible and the facts relied upon must be supported. (See MPEP Section 2144.03 and 37 CFR 1.104(d)(2)).

Significantly, the Court of Appeals for the Federal Circuit in In re Lee, 61 USPQ 21 1430 (Fed. Cir. 2002) reinforced the obligation of a fact finder to develop evidentiary bases for conclusions concerning the application of art to claims. As to certain limitations recited in each of the pending claims, it is respectfully submitted that no evidentiary basis has been provided for the manner in which the teachings of the cited art is modified and in fact, the cited art teaches away from the modification suggested by the Examiner.

B. Group I: Claims 1-3, 5, 7-10, 36 and 37

1. § 102(e): Drasler et al.

Independent claim 1 and dependent claims 2, 3, 5, 7-10 and 36 are believed to be allowable over the Drasler et al. patent. It is respectfully submitted that the Drasler et al. patent does not qualify as § 102(e) art since it does not teach each and every limitation recited in claims 1, 2, 3, 5, 7-10 and 36.

Significantly, Drasler et al. does not teach a medical apparatus including at least a pair of adjacent generally longitudinal members each having a circumferential width, wherein the radial thickness is greater than the circumferential width as recited in claim 1 and each of its dependent

claims. On the contrary, the Drasler et al. reference merely teaches a hinge with a radial thickness greater than its circumferential width.

Additionally, it is significant that claim 36 recites a medical apparatus including at least a pair of adjacent generally longitudinal members each having a circumferential width, wherein the radial thickness is greater than a circumferential width and wherein at least one of the at least a pair of longitudinal members extend a length of one cell of the open cells. Clearly, the cited Drasler et al. reference does not teach longitudinal members having a radial thickness greater than a circumferential width, the longitudinal members extending a length of one cell of the medical apparatus. On the contrary, as stated, the Drasler et al. reference discloses a hinge which has a radial thickness greater than a circumferential width but such hinge does not extend the length of a cell of the Drasler et al. stent.

Therefore, the Drasler et al. patent does not teach each and every limitation recited in claims 1, 2, 3, 5, 7-10 and 36 and as such, it is respectfully submitted that these claims are allowable over the cited art.

2. § 103(a): Drasler et al.

Claim 37 has been rejected under § 103(a) as being unpatentable over Drasler et al.

It is to be recognized, however, that MPEP 2145 while referencing MPEP 2143.01, states that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine referenced teachings. It is additionally noted that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Additionally, "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill in the art at the time the claimed invention was made' because the references relied

upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facia* case of obviousness without some objective reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion or to combine references."

It is also believed to be highly significant to the rejection of claim 37 that MPEP 2143.01 additionally states that "If the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facia* obvious."

The Drasler et al. reference teaches a balloon-expandable stent including a hinge providing the strength to support a blood vessel and resist vessel contraction as well as to provide the stent with non-crush characteristics in combination with struts configured to provide the stent with a compression yield force that could be properly overcome by balloon expansion (See Col. 7, line 50 et seq.). The Drasler et al. reference also teaches a self-expandable stent including a hinge having a greater radial dimension than the struts to resist the formation of an oval cross section associated with crush deformation (See Col. 8, line 66 et seq.).

Accordingly, it is respectfully submitted that rejecting claim 37 for obviousness in view of the Drasler et al. reference is misplaced as one of ordinary skill in the art would not have modified the teachings of the Drasler et al. reference as suggested by the Examiner. That is, one of ordinary skill in the art would not modify the apparatus disclosed in the Drasler et al. patent to provide a hinge structure having a profile the same as that of a strut. So modifying Drasler et al. would be completely contrary to its teachings since a balloon-expandable stent would consequently lack struts having a compression yield force designed to be overcome by balloon expansion. Moreover, a Drasler et al. self-expandable stent so modified would lack a hinge

having a greater radial dimension than that of the struts to resist formation of an oval cross-section.

Thus, in accordance with MPEP 2143, it is respectfully submitted that a *prima facia* case of obviousness has not been established with respect to claim 37 because modifying the Drasler et al. patent as suggested by the Examiner would change the principle operation of the structure disclosed in Drasler et al. Therefore, it is respectfully submitted that the rejection of claim 37 was made in error.

C. Group II: Claims 12-15 and 38

1. § 102(e): Drasler et al.

Independent claim 12 and its dependent claims 13-18 and 38 recite a single-piece prosthesis including a plurality of circumferential spaced beams, adjacent beams including forward merge sections and aft merge sections as well as at least a pair of adjacent circumferential spaced beams each having a circumferential width less than the radial thickness. The Drasler et al. reference fails to anticipate claim 12 and its dependent claims since it merely teaches hinges having a circumferential width less than a radial thickness and not the recited adjacent beams having both forward and aft merge sections as well as a circumferential width less than a radial thickness.

Moreover, claim 38 recites an endoprosthesis including beams having a circumferential width less than a radial thickness, wherein at least one of the beams has a generally uniform cross-section along its length. In view of the Examiner's position that "hinges 23 are portions of the struts forming the Drasler stent" and since the Drasler et al. reference clearly teaches hinges having a different cross-sectional profile than the struts forming the disclosed Drasler et al. stent, Drasler et al. clearly does not teach an endoprosthesis wherein one of the plurality of circumferential beams have a generally uniform cross-section along its length.

Therefore, it is respectfully submitted that Drasler et al. does not anticipate claims 12-18 and 38 under § 102(e). Accordingly, it is respectfully submitted that claims 12-18 and 38 define subject matter which is allowable over the cited Drasler et al. patent.

D. Group III: Claims 17, 20, 22, 23 and 39

1. § 102(e): Drasler et al.

Claim 17 and its dependent claims 20, 27 and 39 recite a single piece endoprosthesis including a plurality of longitudinal beams, at least a pair of adjacent longitudinal beams each having a radial thickness greater than a circumferential width, the endoprosthesis having an expanded configuration wherein each beam is mostly curved throughout its length. In addition to lacking beams having a radial thickness which is greater than a circumferential width, the Drasler et al. reference also is lacking the teaching of an endoprosthesis having expanded configuration wherein each beam is mostly curved throughout its length. Clearly, since they include straight sections along their length, the struts disclosed in the Drasler et al. reference do not meet these claim limitations.

Furthermore, claim 39 recites an endoprosthesis including beams having a circumferential width less than a radial thickness, wherein at least one of the beams has a generally uniform cross-section along its length. In view of the Examiner's position that "hinges 23 are portions of the struts forming the Drasler stent" and since the Drasler et al. reference clearly teaches hinges having a different cross-sectional profile than the struts forming the disclosed Drasler et al. stent, Drasler et al. clearly does not teach an endoprosthesis wherein one of the plurality of circumferential beams have a generally uniform cross-section along its length.

Accordingly, it is respectfully submitted that the Drasler et al. reference does not teach each and every limitation recited in claim 17, 20, 27 and 39 as is required and § 102(e). As such,

it is respectfully submitted that claims 17, 20, 27 and 39 are allowable over the cited Drasler et al. reference.

CONCLUSION

For all the reasons stated above, Applicants respectfully submit that the Examiner has erred in rejecting claims 1-3, 5, 7-10, 12-15, 17, 20, 22, 23, 36, 38 and 39. It is respectfully requested that the Board reverse the rejection of these claims and thus, pass pending claims 1-24 and 36-39 to issue.

Respectfully submitted,

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VIII. CLAIMS

Claim 1 (previously presented): A medical apparatus, comprising:

a hollow cylinder defining an inner diameter, an outer diameter, and a radial thickness;

open cells removed from the hollow cylinder defining generally longitudinal members in remaining material of the cylinder and defining connection points between adjacent longitudinal members, the connection points not being created by spot welding or film gluing and lacking bulk and stress concentrations associated with conventional joint techniques; and

at least a pair of adjacent generally longitudinal members each having a circumferential width, wherein the radial thickness is greater than the circumferential width.

Claim 2 (previously presented): The medical apparatus of claim 1, wherein each generally longitudinal member joins with adjacent generally longitudinal members to form merge sections.

Claim 3 (previously presented): The medical apparatus of claim 2, wherein the generally longitudinal members and merge sections form a continuous cylindrical structure.

Claim 4 (withdrawn): The medical apparatus of claim 2, wherein each generally longitudinal member only joins with opposing adjacent members at opposing ends of the generally longitudinal member.

Claim 5 (previously presented): The medical apparatus of claim 2, wherein each generally longitudinal member alternately joins with alternating adjacent generally longitudinal members throughout the length of the generally longitudinal member.

Claim 6 (original): The medical apparatus of claim 1, wherein the generally longitudinal members each comprise:

two curved sections of opposing curvature joined end-to-end.

Claim 7 (previously presented): The medical apparatus of claim 1, wherein the generally longitudinal members each comprise:

at least three curved sections each joined end-to-end with curved sections having opposing curvature.

Claim 8 (previously presented): The medical apparatus of claim 1, further comprising:

a compressed condition defining a reduced inner diameter and outer diameter, wherein the endoprosthesis is capable of compression to the compressed condition.

Claim 9 (previously presented): The medical apparatus of claim 1, further comprising:

an expanded condition defining an increased inner diameter and outer diameter, wherein the endoprosthesis is capable of expansion to the expanded condition.

Claim 10 (previously presented): The medical apparatus of claim 9, wherein the expanded condition further defines a conical shape of the endoprosthesis.

Claim 11 (withdrawn): The medical apparatus of claim 1, wherein the circumferential width of at least one generally longitudinally extending member varies along a length thereof.

Claim 12 (previously presented): A single-piece cylindrical endoprosthesis comprising:

a plurality of circumferential spaced beams each defining a longitudinal length, a forward end, a rear end, and a radial thickness, at least a pair of adjacent circumferential spaced beams each having a circumferential width less than the radial thickness;

a plurality of forward merge sections formed by the front ends of two adjacent beams; and

a plurality of aft merge sections formed by the rear ends of two adjacent beams;

whereby the combination of beams, forward merge sections and aft merge sections form a continuous cylindrical structure and define connection points not being created by spot welding

or film gluing and lacking bulk and stress concentrations associated with conventional joining techniques.

Claim 13 (previously presented): The endoprosthesis of claim 12, further comprising:

a plurality of middle merge sections formed from the intermittent joining of adjacent beams.

Claim 14 (previously presented): The endoprosthesis of claim 12, wherein the beams further define at least one pair of curved sections of opposing curvature joined end-to-end.

Claim 15 (previously presented): The endoprosthesis of claim 14, wherein the point at which the curved sections meet defines an inflection point.

Claim 16 (withdrawn): The endoprosthesis of claim 12, wherein the circumferential width of at least one beam is varied along its length.

Claim 17 (previously presented): A single piece endoprosthesis comprising:

a plurality of longitudinal beams connected in a cylindrical structure to define connection points not being created by spot welding or film gluing and lacking bulk and stress concentrations associated with conventional joining techniques, at least a pair of adjacent longitudinal beams each having a circumferential width and a radial thickness, wherein the radial thickness is greater than the circumferential width;

an expanded configuration wherein each beam is mostly curved throughout its length.

Claim 18 (withdrawn): The endoprosthesis of claim 17, wherein the beams are prevented from overlapping in the compressed configuration by having a thickness greater than their width.

Claim 19 (withdrawn): The endoprosthesis of claim 18, wherein each beam defines a width and a thickness which at least one-third times the width.

Claim 20 (previously presented): The endoprosthesis of claim 17, wherein the beams are continuously curved when in the expanded condition.

Claim 21 (withdrawn): The endoprosthesis of claim 17, wherein the beams are uniformly bent throughout their length when in the expanded condition.

Claim 22 (previously presented): The endoprosthesis of claim 17, wherein the beams are free from stress concentrations in the expanded configuration.

Claim 23 (previously presented): The endoprosthesis of claim 17, wherein the expanded configuration defines a conical shape.

Claim 24 (withdrawn): The endoprosthesis of claim 17, wherein at least one beam has a thickness that varies along its length.

Claims 25-35 (canceled)

Claim 36 (previously presented): The medical apparatus of claim 1, wherein at least one of the at least a pair of longitudinal members extend a length of one cell of the open cells.

Claim 37 (previously presented): The medical apparatus of claim 1, wherein the medical apparatus lacks a hinge structure having a profile which differs from that of the pair of longitudinal struts.

Claim 38 (previously presented): The endoprosthesis of claim 12, wherein at least one of the plurality of circumferential spaced beams has a generally uniform cross-section along its length.

Claim 39 (previously presented): The endoprosthesis of claim 17, wherein at least one of the plurality of longitudinal beams has a generally uniform cross-section along its length.

AFS JFW

Doc Code:

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Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/546,966
Filing Date	4/11/2000
First Named Inventor	David T. Pollock
Art Unit	3731
Examiner Name	Vy Q. Bui
Total Number of Pages in This Submission: 16	Attorney Docket Number: ENDOS-51639 (GES-0012)

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
  - [X] Fee Attached
- [ ] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
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- [ ] After Allowance Communication to TC
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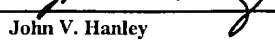
Signature			
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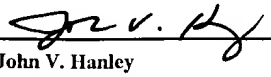
Signature			
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Fees pursuant to the Consolidated Appropriatons Act, 2005 (H.R. 4818).

FEE TRANSMITTAL for FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) $500.00

Complete if Known	
Application Number	09/546,966
Filing Date	4/11/2000
First Named Inventor	David T. Pollock
Examiner Name	Vy Q. Bui
Art Unit	3731
Attorney Docket No.	ENDOS-51639

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: Fulwider Patton LLP

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x $50.00	=	$0.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x $200.00	=	$0.00

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

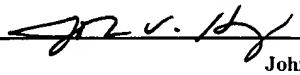
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listing under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
_____	- 100 =	0	/ 50	0	(round up to a whole number) x	$250.00	=	$0.00

4. OTHER FEE(S)

	Fee Paid ($)
Non-English specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief	$500.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	38,171	Telephone	310-824-5555
Name (Print/Type)	John V. Hanley			Date	12/20/2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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